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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,546	07/13/2007	Helge Zieler	30844/30003A	8488
4743 7590 12/23/2010 MARSHALL, GERSTEIN & BORUN LLP 233 SOUTH WACKER DRIVE 6300 WILLIS TOWER CHICAGO, IL 60606-6357				
EXAMINER				
PAGE, BRENT T				
ART UNIT		PAPER NUMBER		
1638				
NOTIFICATION DATE		DELIVERY MODE		
12/23/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mgbdocket@marshallip.com

Office Action Summary

Application No.

10/590,546

Applicant(s)

ZIELER ET AL.

Examiner

BRENT PAGE

Art Unit

1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 October 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 10, 11, 14-16, 19, 25, 30, 39, 43-46, 54, 56-62, 66, 89, 90, 93, and 96 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 10-11, 14-16, 19, 25, 30, 39, 43-46, 54, 56-62, 66, 89-90, 93, and 96 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The Reply filed by Applicant on 10/06/2010 selecting SEQ ID NO:24 without traverse is hereby acknowledged. Although a closer inspection of the state of the art has resulted in new and a new enablement and new written description rejection, it is noted that the art is specific to soybean and specific to the SEQ ID NO selected herein and therefore does not in itself require the action to be made Non-Final. However, a closer inspection of the claims has necessitated a new ground of rejection under 35 USC 101 that results in the office action being made Non-Final.

Claims 1-3, 7, 10-11, 14-16, 19, 25, 30, 39, 43-46, 54, 56-62, 66, 89-90, 93, and 96 are pending and examined herein on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 54, and 56-62 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims are broadly drawn to a "part of the plant" a "meiocyte, gamete, ovule, pollen, or endosperm of the plant" "a seed embryo or propagule of the plant" and progeny from a transgenic plant. However due to Mendelian inheritance of the minichromosome, some seeds and propagules produced by a transgenic plant will not have a copy of the minichromosomes, particularly wherein the claims are only drawn to 90% transmission rate, and will thus be indistinguishable from naturally occurring seeds, plant parts or progeny. Accordingly, the claims are drawn to a product of nature, which is non-statutory subject matter.

See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. V. Kalo inoculant Co.*, 233 U.S. 127 (1948), and *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931).

This rejection can be overcome by amendment of the claims to indicate that the seeds, parts, propagules and progeny comprise said mini-chromosome.

Claim Rejections - 35 USC § 112-2nd paragraph

Applicant's arguments, see page 19 of the response, filed 06/07/2010, with respect to indefiniteness have been fully considered and are persuasive when taken together with the claim amendments. The rejection of newly cancelled claim 6 has been withdrawn.

Claim Rejections - 35 USC § 112-enablement

Claims 1-3, 7, 10-11, 14-16, 19, 25, 30, 39, 43-46, 54, 56-62, 89-90, 93 and 96 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to a plant comprising any minichromosome of any size below 1000 kilobases comprising SEQ ID NO:24 or a fragment of 20-360 nucleotides of SEQ ID NO:24 in any copy number wherein the mini-chromosome is functional, stable, autonomous and has a transmission efficiency of 90%.

In contrast, the specification provides guidance for specific BAC clones containing specific arrangements of known centromere repeats for use as centromeric DNA, specific telomeric repeats, and specific origin of replication sequences for function as a minichromosome. The specification does not give guidance for any minichromosome with any DNA composition as broadly claimed or any number of repeats, or small fragments as small as 20 bases of SEQ ID NO:24 wherein the sequence confers the ability of segregating to daughter cells to the mini-chromosomes, nor does the specification indicate which sequences are absolutely required for centromere function, telomere function or origin of replication function to enable one of skill in the art over the full scope of the claims. For example, no centromere contributions under about 50kb in length are shown to function as centromeres in a minichromosome in a plant cell.

A recent article (2010, Tek et al Chromosome Research 18:337-347) on soybean centromeres (SEQ ID NO:24 is a soybean centromeric repeat) discloses the sequences believed to be necessary for centromere function in soybeans and disclose that 3 distinct repeats appear to be necessary for centromere function, GmCent-1, GmCent-4 and GmCR and state "it appears that soybean centromeres are primarily composed of two satellite sequences with relatively fewere interruptions by retrotransposon-related elements. Further investigations are required to determine the composition and contribution of GmCR elements in soybean centromeres" (see page 345 end of column 1 and beginning of column 2). It is of note that this study did not merely map the location of these repeats but did so in conjunction with the localization of CENH3 and showed

interaction of CENH3 with said sequences and further, state "CENH3 is at the foundation of a complex network of proteins that forms a functional kinetochore" (see page 340, last paragraph). This study shows that the location of a sequences in the centromeric region is not sufficient to confer centromere function and that further, it is possible that more than one sequence that interacts with CENH3 may be necessary for kinetochore formation in soybeans.

The instantly claimed sequence is of the GmCent-1 family.

Given the state of the art at the time of filing, the breadth of the claims, the lack of working examples and the unpredictability it would have been undue experimentation for one of skill in the art to evaluate sequence composition, copy number and further, to evaluate such unknown sequences in resultant plants for use as mini-chromosomes with 90% transmission efficiency rate as claimed. The required sequences were unknown in the art at the time of filing and not supplied in the instant application, and so the claims as currently written are not enabled for mini-chromosome function in any plant species including glycine max.

It is suggested that if a particular sequence composition that is disclosed in the instant application was shown to function as an autonomous mini-chromosome and fit the sequence criteria laid out in Tek et al, that the claims should be limited to this sequence composition for enablement consideration.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. It is also noted, that merely identifying

sequences that react with CENH3, in light of the art above, does not appear to be sufficient to give guidance as to sequences that confer centromeric function.

Claim Rejections - 35 USC § 112-written description

Claims 1-3, 7, 10-11, 14-16, 19, 25, 30, 39, 43-46, 54, 56-62, 89-90, 93 and 96 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a plant comprising any minichromosome of any size below 1000 kilobases comprising SEQ ID NO:24 or a fragment of 20-360 nucleotides of SEQ ID NO:24 in any copy number wherein the mini-chromosome is functional, stable, autonomous and has a transmission efficiency of 90%.

In contrast the specification does not provide any working examples of autonomous mini-chromosomes segregating in the daughter cells of any plants. The specification does not describe all the necessary sequences for such autonomous and segregation function and does not describe what is required for the claimed function.

While the specification does describe BAC clones that comprise sequences that retain the ability to segregate in daughter cells, the specification does not fully describe the required sequences within the BAC clones that are required for centromere function.

The genus claimed, literally any sequence of any size comprising as little as 20 bases of SEQ ID NO:24 encompasses literally millions of embodiments. There are no working examples, however of autonomous mini-chromosomes in plants with at least 90% transmission efficiency. In the absence of working examples the specification should at least describe the required structural features that are necessary for the claimed function. The specification describes obtaining a consensus sequence for one type of repeat, but does not describe the other repeats that appear to be necessary for soybean centromere function as discussed in the above enablement rejection.

Accordingly, the specification as currently written lacks adequate written description for the claims as currently written.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention "requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of the members of the genus." *Id.*

Finally, the court held:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or a recitation of structural features common to members of the genus, which features constitute a substantial portion of the genus. *Id.*

See also MPEP section 2163, page 174 of chapter 2100 of the August 2005 version, column 1, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

See also *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at 1021, (Fed. Cir. 1991) where it is taught that a gene (which includes a promoter) is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Given the claim breadth and lack of description as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. In the instant case, it is also noted that wherein there appear to be required additional sequences for centromere function and such sequences are not part of the claims and are not clearly described in the specification to disclose that they are essential for function, falls short of the requirements for written description of Applicants claimed invention.

Claim Rejections - 35 USC § 102

Applicant's arguments, see pages 13-14 of the response, filed 06/07/2010, with respect to anticipation have been fully considered and are persuasive when taken together with the claim amendments. The rejection of the claims has been withdrawn under 35 USC 102 as being anticipated by the prior art, due to the failure of the prior art to teach or reasonably suggest mini-chromosomes with at least a fragment of SEQ ID NO:24 conferring centromere function.

Claim Rejections - 35 USC § 103

Applicant's arguments, see page 14 of the response, filed 06/07/2010, with respect to obviousness have been fully considered and are persuasive when taken together with the claim amendments. The rejection of the claims has been withdrawn under 35 USC 103 as being obvious over the prior art, due to the failure of the prior art to teach or reasonably suggest mini-chromosomes with at least a fragment of SEQ ID NO:24 conferring centromere function.

Double Patenting

The claim amendments entered herein render the double patenting rejections of record moot since none of the claims include mini-chromosomes comprising at least 20 bases of SEQ ID NO:24.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRENT PAGE whose telephone number is (571)272-5914. The examiner can normally be reached on Monday-Friday 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571)-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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